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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
SENATE BILL 472 (CHAPTER 470, STATUTES OF 2007)
PUBLIC FORUM
MINUTES

DATE: April 12, 2008

LOCATION: Wally Pond Irvington Community Center
41885 Blacow Road
Fremont, CA 94538

BOARD MEMBERS PRESENT:
William Powers, Public Member, President
Ruth M. Conroy, PharmD, Vice President
Kenneth H. Schell, PharmD
Susan L. Ravnan, PharmD

BOARD MEMBERS NOT PRESENT:
Robert Swart, PharmD
Shirley Wheat, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Tina Thomas, Staff Analyst

BOARD MEMBERS IN AUDIENCE:
Stanley Goldenberg, RPh
Henry Hough, Public Member
James Burgard, Public Member

Dr. Schell called the meeting to order at 10:00a.m.

Invitation to Participate in the Redesign of Prescription Container Labels
Dr. Schell explained the purpose of the meeting. Dr. Schell stressed the importance of this law and the public forums the board will hold statewide. It is the Board of Pharmacy's goal to create a dynamic workable solution to standardize prescription labeling.

Presentations of SCR 49 findings, and need for patients to understand their drug therapy as a source of reducing prescription errors.
Mike Negrete with the Pharmacy Foundation of California spoke on behalf the Medication Error Committee resulting from SCR 49, and shared their findings.

Dr. Negrete reviewed the definition of medication error. He also reviewed the background of SCR49, the panel's focus on outpatient setting and need for patient-centered prescription labels. The commitee reviewed key systems, which included healthcare training and licensure, healthcare provider payments and incentives, transcription and transmission of prescriptions, and education to the consumer. Dr. Negrete reviewed the seven goals identified by the panel, as well as their eleven recommendations (3 directly related to consumer education) with relation to prescription errors. Dr. Negrete discussed those consumer education related goals, where communication improvements are needed. He noted the issue of poor communication between prescribers, pharmacists and patients whereas such poor communication causes patient on-adherence. Dr. Negrete gave examples of pictographs developed by the USP and the lack of clarity of the pictures and text even among those with high health literacy. Dr. Negrete invited the audience to review the full report of the panel's research on their web site.

Joan Lee (Gray Panthers) commented that patients frequently waive consultations, or patients are placed in the situation of signing a waiver to consultation because they are given an option. Dr. Negrete replied that this issue was a big discussion for the panel. He noted that the panel considered that the only person allowing the patient to waive the consult must be a pharmacist.

Ms. Herold pointed out that if a pharmacist fails to in initiate a consultation when required, it is a violation of law. She stressed that the board does not want to put the burden solely on the patient to determine whether a consultation is needed. The Board of Pharmacy provided the Notice to Consumers poster to every pharmacy, which includes five questions that every patient should read. These questions are aimed at improving patient understanding of their drug therapy through patient consultation.

Ms. Lee noted that Gray Panthers is creating a survey that relates to the consultation process in pharmacies.

Stephen Rosati commented that owners and directors of pharmacy chains should get the information on that screening for consultation violates California law.

Joshua Room asked whether Dr. Negrete is aware of any compilation of all the various label sizes and space needed on the labels. Dr. Negrete responded that he could not find any such information. Mr.Room noted that typically board regulations are developed based on a set of minimums previously defined.

Ms. Herold stated the request to hear from the public and what works for them on the label. She referenced the more than 50 different sizes and shapes of pharmacy containers displayed for the subcomittee and stated that the corresponding labels for these containers would be similarly diverse.

Michael Villaire (Institute for Healthcare Advancement) referenced a recent study where the findings indicated the pharmacy's logo, address, and phone number as the largest items on the label.

Mr. Rosati noted to be cautious with compression ability, and that some things can be compressed, but not others. Mr. Rosati suggested an 8 point font, to avoid compressing the important information (i.e., sig.)

Ms. Lee shared a piece of paper with small point font, and voiced her opinion that it's too small. Ms. Lee requested that the size of the font be in relation to the importance of the material, and that the sig and warnings be kept larger

Steve Gray (Kaiser Permanente) pointed that it is virtually impossible to accomplish all of the goals mentioned so far. Dr.Gray shared the results of their internal studies, which included the issue of portability when patients travel with their prescriptions. He also pointed out the other types of prescription containers, and discussed auxiliary labels. Dr. Gray mentioned the issue of gaining consensus from the various physicians, nurses and pharmacists on how dosages. Dr. Gray reiterated the concern over how much can be accomplished, and would like to see us go back to the basics of what we want to accomplish. Mr. Room asked Dr. Gray about any studies showing any difference in prescription errors with the verbal description mandate. He shared that they did notice a slight decrease in dispensing errors.

Mr. Rosati provided a rough estimate of 75 cents per prescription, if all prescriptions had pictures placed on labels. Mr. Rosati suggested a picture be added to the label instead of the currently required description of the pill.

Ms. Herold asked Dr. Gray who makes the decision on which container the medicine will go into. Dr. Gray stated that it some factors include what sizes of containers a pharmacy chooses to stock, automated filling systems are used, and the patients' requests for portability.

Cookie Quandt (Longs Drugs) commented that some pharmacies do use automation, thus technology determines the size of the bottle.

Dr. Gray and Dr. Negrete noted issues with placing pills into multiple bottles due to large quantities or for travel purposes. Patients often will not carry large containers and so will place medicine dispensed in a large container into unlabeled smaller containers.

Mr. Room made the suggestion of multiple labels being dispensed to patients with medicine so patient-selected containers chosen for convenience could also have a label applied by patients.

Ms. Quandt commented on the concern of patients' mixing pills into one container.

Requests for Public Comment on the Following: What works on prescription container labels? What does not?

Ramon Castellblanch (San Francisco State University) stated that based on his research and the materials for this meeting, there is a consensus on what contents and formatting of labels should be. The labels should be patient friendly, with relation to indication, benefits of the prescription, duration, and the adverse effects. He listed other components needed relating to format, font, terminology and the need for written inserts. Mr. Castellblanch shared the current development being conducted to create a universal medication schedule based on time of day (morning and evening or breakfast, lunch, dinner, and bedtime).

Dr. Schell asked the audience for one specific item that is currently helping them to take their medications.

Ms. Lee noted the confusion over generic names being listed on the label, and would rather have the purpose of the pill listed than a chemical name that has little value to her. Ms. Lee stated that the directions for use is the one thing that is most crucial to her.

Remarks from the Honorable Ellen Corbett, California Senator, District 10
Senator Corbett, the author of Senate Bill 472, addressed the audience. Senator Corbett thanked everyone attending the forum for their advocacy of SB 472. Senator Corbett gave a brief history of the bill and the reason for its creation. She also gave specific thanks to those heavily involved in the development of the bill. She pointed out the issue of language access and visual impairment, make it difficult for some consumers to understand the medicine they take.

Continuation of discussion on what is currently most crucial piece of label to forum members.

Mr. Rosati felt that the sig text in bold printing and all caps was crucial. He also suggested that pharmacies tape labels with transparent tape to avoid ruboff.

Vanessa Cajino (Latino Coalition) commented that translation of directions is necessary for non-English speaking patients.

Dr. Gray stated that the name of the pharmacy and a prescription order number is crucial in order to easily request refills.

Ms. Lee added that the expiration date of the medication is important, for those prescriptions who are not used as often.

Mr. Castellblanch suggested the importance of the indication of each type of prescription, dosing, schedule, and adverse effects.

Dr. Negrete commented on the importance of communicating adverse effects in an effective way. He gave the example of “2%” vs. “some”, and the concern over leaving the terminology of “some”. The concern over leaving terminology of “some” as too open and infers for more frequent problems than 2 percent would indicate, making patients overly concerned.

Ernie Tom (Ralphs Pharmacies) stated that everything on the label right now “works,” because it is all needed information.

Mr. Villaire pointed out the loss of control once the prescription goes home with a patient. Mr. Villaire stated that even consultations may be later forgotten by patients after they leave (or have questions later). Mr Villaire suggested a phone number that goes directly to a pharmacy for consultations or questions relating to their prescription. He suggested a second set of inserts written at a lower reading level, as well as a follow-up survey with patients to determine proper use of medications. Mr. Villaire also suggested text messages to patients to remind them to take their prescriptions, as well as follow-up phone calls to see how a prescription is working for patient. He also suggested additional focus groups to get more information from public. Mr. Villaire urged the board to go out to the public for more input.

Mr. Room asked if there is anything on labels now that is unnecessary. He suggested the name of the drug manufacturer as an example.

Dr. Negrete brought up the issue of a need for that information in the case of a recall. Mr. Room pointed out that the pharmacy will initiate a recall and knows this information.

Ms. Lee commented that knowing where a drug is manufactured these days may be important to some consumers, due to the current degree of concern over imported drugs. Mr. Lee suggested putting the origin of the label on inserts.

Dr. Tom noted that he has had consumers indicate an allergic reaction to drugs from certain manufacturers, so the name of the manufacturer is important.

The comment was made that, in the event of an allergic reaction, most consumers will contact their pharmacy in order to find out what manufacturer the drug came from.

A discussion ensued regarding providing a manufacturer code, as opposed to the manufacturer's name (on the label).

Mr. Rosati noted excessive phone numbers and addresses of the patient on some pharmacy labels, and suggested placing an auxiliary label on the side.

Mr. Rosati commented that the bar code should be only thing placed vertically on the bottle.

President Powers asked about the source of funding for the insert, as it needs to be geared towards benefiting the patient, not the manufacturer. He also asked if there is information on the studies in Canada on the effectiveness on auxiliary labels.

Mr. Castellblanch shared the success of standardized (patient-friendly) risk and benefit leaflets required by the manufacturers there. He suggested the ability for us to utilize their leaflets here in the US.

Dr. Quandt noted that most chain pharmacies use information provided by First Data Bank, and is not funded by the manufacturer.

A discussion ensued on additional inserts currently provided, First Data Bank and MedGuide.

Dr. Negrete noted that First Data Bank has launched the World Free of Medication Errors campaign, with a conference occurring in a couple of weeks. It was suggested to ask a representative to come to a Forum and speak on how the campaign is being applied to their processes. Dr. Negrete also commented on the previous discussion of manufacturer information provided. He stated that some patients are very particular about having the right medications from the right manufacturer, and that changes to that can have a physiological affect on them. He also commented that we must be careful on providing too much information to a patient, and ensuring that we only place information on the label that is crucial to the patient.

Ms. Lee requested that colored fonts be avoided with regard to warning labels. She suggested larger font as crucial.

Mr. Castellblanch shared a suggestion of a label on the back side of the bottle for the warning labels.

Dr. Negrete noted the importance of being careful not to go overboard on warnings. He stated that this can cause the patient to be overly concerned and possibly choose not to take their medicine.

Discussion ensued regarding the indication being placed on the label.

Mr. Room referenced the idea of the universal medical schedule. He raised the question of how to determine the language for medications where the directions are NOT to be taken during meal time. Mr. Castellblanch responded that 72% of prescriptions would be satisfied with a breakfast/lunch/supper/bedtime schedule. The directions of "take as needed" or "take as directed" brings the total up to 85% of all prescriptions.

Mr. Room stated that he understood the survey conducted only referred to directions that involved medication being taken certain times of day (and not whether or not it was to be taken with food).

Toni Jette (Kaiser Permanente) stated her concerned about the take with meals schedule idea. She conducted a survey among a small group, and determined that some patients skip meals and others have several meals a day. She noted that economics is also an issue, as patients will skip doses because they can't afford to take all daily doses.

Mr. Villaire noted the universal schedule as a first step, and that it does minimally address the issue of health literacy.

Caroline Lee noted that some pharmacies serving specific populations write directly on the labels what the prescription is for, what it's treating, how many times a day, plus the actual times. This makes the directions time oriented, not meal oriented. Ms. Lee feels that it's a good idea to have the label state what the medicine is used for to be on the label.

Mr. Castellblanch noted that the universal schedule is only a proposal at this point, and that the author of the schedule had attempted the time oriented approach, but had less success with it. He also noted that the author included a field for addressing critical issues in relation to how the medication should be taken.

Ms. Joan Lee noted her concern as a patient of how to break out the total time within a 24-hour day for taking her doses of medication.

Dr. Conroy noted the concern over having to pick times for patients to take medication, because people go to bed and wake up at different times, for example. Dr. Conroy brought up the awareness of pharmacies not using certain terminology on labels that are beyond a 5th grade reading level (i.e., "sparingly"). She also mentioned the varying opinions on whether "daily" and "once daily" have the same meaning.

Dr. Gray discussed the issue of "as directed" and what means to pharmacists. There was significant discrepancy in what the sig codes really mean to different pharmacists.

Dr. Negrete suggested the need for a consult between prescriber and pharmacist, to clarify the understanding of the sig as listed.

Mr. Castellblanch reiterated the concern over differences in verbiage, and pointed out that the universal schedule concept would assist in resolving that.

Dr. Gray discussed the reduction of patient wait time due to technology and e-prescribing. He noted that, if we ask for patient input on a label, it may increase patient wait time again.

How can prescription container labels be improved to make them patient-centered?

Dr. Schell began the discussion on literacy versus comprehension, and what we can for those people with people with low health literacy.

Dr. Negrete indicated that the SCR 49 panel discussed encouraging consumers to seek out pharmacies that share their language and culture. The panel also discussed increasing awareness in the pharmacies on the need for translators. They did not address the issues of visually impaired patients.

Mr. Villaire stressed the use of the “teach back method,” where patients state back what they understood. Mr. Villaire suggested the “teach back method” be used at consultations.

Dr. Schell asked the group if that is being done.

Dr. Gray stated that consultation competitions for pharmacy school students, the “teach back method” is within pharmacy practices. Dr. Gray suggested that this may be because patients respond defensively to that method, so pharmacists get discouraged. Dr. Gray also raised the issue of retention, as well as the issue of caregivers who are not English-speaking. He stated that many pharmacists may not know that they are legally required to provide translation services, as well as accommodations for the visually impaired.

Mr. Room and Ms. Herold initiated a discussion and display of pictograms and the confusion and lack of clarity over what the pictures are supposed to indicate.

Vanessa Cajina (Latino Coalition for a Healthy California) shared that there is research coming out from UCSF and Fresno and the use of pictograms. Ms. Cajina offered to share the information on that research from those interested.

Ms. Joan Lee stated that she wants to mention the importance of visually impaired patients and would like to ensure that the topic isn’t left out of further discussions. Ms. Lee also reiterated the importance of colored labels for those with vision issues.

Dr. Schell pointed out that comprehension changes as you age, and that we may have to consider different languages that are age-appropriate.

Dr. Gray noted that the visually impaired accommodations are already spelled out in the ADA, and questioned whether we should even need to address this when it is already in the federal law. Dr. Gray indicated that there is an service in Oregon that provide a Braille package insert of a prescription within 48 hours. Ms. Herold suggested that Dr. Gray write an article regarding this for the July newsletter.

Ms. Jette referenced the talking vial for those who are visually impaired.

Dr. Schell began a discussion on what should be done next, and who is going to pay for all this.

Dr. Gray commented that we should wait until we get more input from different parts of state before moving forward. He also stated that we should consider a “test” process.

Mr. Room asked if it might be possible to get software vendors who can participate and give their perspective on labeling space and what’s feasible.

Dr. Gray stated that there are key pharmacy organizations that have computer systems and tools who will sell them. He referenced McKesson’s work in this area and First Data Bank.

Mr. Castellblanch responded to the comment of testing language or pictograms, and stated that if other entities are already working on this, we should use their research findings rather than recreating the wheel.

Ms. Herold reviewed the purpose of this forum and the intent to engage the public. She asked how many public individuals are here, there were only a few. Ms. Herold stated that two press releases wereissued, letters of invitation were sent to a number of community service agencies in the are and use of mailing

lists of the bill's sponsors did not result in desired public participation. She noted that the SB 472 committee is trying to elicit and encourage conversation on this topic. Ms. Herold stated that the board is asking those attending the forum to help bring in their constituencies. She reminded the group of the agreement with Senator Corbett, the bill's author, to hold six public forums independent of board meetings to get the public involved. She also noted that the Director of the Department of Consumer Affairs is planning to hold a board meeting once a year with all of the boards and bureaus present. The date is in November and will include the Medical Board and Nursing Board. Ms. Herold would suggest that the experts attend that meeting to present their research, as it will follow the opportunity to have a few more public forums. Ms. Herold also asked for input on how the future forums should be structured.

Mr. Room shared concern over those organizations. (i.e., Target, CVS) who have developed their own labeling systems that may have intellectual property rights attached. He encouraged us to make sure those companies are included in the discussions. Ms. Herold responded that both the organizations mentioned were contacted at the time the legislation was pending. They are being represented today by an association member.

Heidi Barsuglia (California Retailers Association) shared that those would be involved once we are further in the process.

Mr. Castellblanch stated that he wasn't aware of CARA (California Alliance of Retired Americans) having been invited to the forums, but would get them involved.

Mr. Villaire suggested the Board go to where people are for other purposes and events, and have board representatives schedule some of these meetings in conjunction with events.

A member of the audience suggested creating posters in pharmacies to advise the public when a meeting will be held in the are.

Dr.Negrete pointed out that SB472 is not on the radar screen for average people right now, which is why they are not attending the forum. Dr. Negrete also referred back to the question of maximum capacity on a label. He calculated that, at 10pt font for all text, you can fit 216 characters which is 36 words on a label (if fully covered with text).

Ms. Lee stated that she is a community member organizer. She said that they do have community forums, which includes groups of seniors who are passionate about having patient-centered labels. She stated that it is just a matter of finding the venues to get the information out.

Dr. Gray discussed getting the insurance companies involved in the forums as well.

Ms. Herold suggested that the pharmacists simply ask their patients on an individual basis.

Dr. Negrete asked about where the National Association of Boards of Pharmacy is on this issue. Ms. Herold stated that we are ahead of their progress, and that they will be putting out a resolution a year from now.

Ms. Herold stated that the panel will need to make some serious decisions in terms of the direction we go. Ms. Herold pointed out that they are not set up to alter what is currently required on the label, and will not be changing the law. She reiterated Mr. Room's concern with regards to Target/CVS and the requirement of a standardized format.

Mr. Room stated that we cannot necessary capture intellectual property rights without agreement by the party who holds it.

Ms. Herold opened the discussion on future meeting dates. She commented that she would like to reach Southern California, and could consider joining with a consumer outreach event. Ms. Herold requested setting a date for May or June, based on the issue of a state budget delay and the lack of funds at that point.

Dr. Gray suggested avoiding downtown governmental areas, because consumers will avoid them. Dr. Gray suggested put the forums in the suburbs or other neutral area.

Mr. Cajina suggested clinics in the Los Angeles area that may be willing to host an event.

Dr. Schell asked if there are any schedule conflicts with large events in the Los Angeles area. Ms. Cajina could not think of any events and will check on Health Fairs, etc. that may be going on. Dr. Schell asked the audience members to review the calendars and upcoming events and respond back to the board with potential opportunities.

Mr. Castellblanch commented that CARA has large meetings, and would be a good venue to present. Ms. Herold asked Mr. Castellblanch to contact her with the information.

The meeting was adjourned at 1:20 p.m.